REMARKS

Applicant acknowledges that claim 12 remains withdrawn from consideration as drawn to a non-elected invention and that claims 4, 11, 37, 38 and 41 of the pending claims are currently under examination. It is further acknowledged that the rejection of claims 4, 11, 34, 37-38 and 41 under the second paragraph of 35 USC 112 as being vague and indefinite has been withdrawn.

The rejection of claims 4, 11, 34, 37-38 and 41 under the first paragraph of 35 USC 112 for lack of enablement for methods of detecting HCV in a biological sample by treatment with a treatment solution and reaction buffer wherein the treatment solution inactivates antibodies present in the sample is respectfully traversed.

The Examiner makes reference to page 48 of the specification which gives an example of the reaction buffer as consisting of 100mM sodium phosphate buffer, ph 7.3, containing 0.15MNaCl, 1% BSA, 0.5% Casein-Na, 0.05% Tween 20 and 1M Tris. The Examiner alleges that the reaction buffer should be limited to this example and an example of the treatment solution as consisting of guanidine hydrochloride, HCL, Triton X 100 and Tween 20 does not reasonably provide enablement for methods of detecting HCV utilizing treatment solutions or reaction buffers other than those as set forth on page 48 and does not enable any methods for detecting HBV.

This application is currently pending based on filing a Request for Continuing Examination under 37 CFR 1.114 of the parent application serial number 09/269,897 filed on April 2, 1999. During prosecution of the parent application, the Examiner in an office action dated July 25, 2002, Paper No. 15, rejected most of the same claims presently being rejected under 35 USC 112, first paragraph, stating that:

"....because the specification, while being enabling for treating a sample containing HCV or HBV with a treatment solution to obtain a sample suitable for detection with an antibody (probe), does not reasonably provide enablement for a method for treating solutions containing any virus **(other than HCV or HBV)** with a treatment solution to obtain a sample suitable for detection with all probes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification effectively demonstrates that the claimed method is effective in releasing the core antigens of HCV and HBV. Said antigens were further demonstrated to bind with anti-HCV and anti-HBV antibodies. The specification is very detailed in outlining the concentration of the various components of the treatment solution that need to be used in order to effectively release the antigens from the intact virus while maintaining its immuno-structure. However, the specification is silent on what components and concentrations of said components, if any, would be needed to achieve the same results if another virus were being tested for." *(Underlining added for emphasis.)*

Although the Examiner has earlier clearly admitted in the above office action that the specification effectively demonstrates the claimed method as being effective in releasing the core antigens for both HCV and HBV but not for other viruses, the Examiner has apparently changed his mind but has not provided any prior art to support the reversal of his opinion. Instead, the Examiner now specifically states on page 5 that "the specification is only enabling for methods of detecting HCV in a biological sample by treating such sample with a treatment solution and a reaction buffer" based upon only the specific limitation set forth on page 48 and that, with regard to HBV, the specification is not enabling for any method of detecting HBV without undue experimentation.

The Examiner has clearly reversed his own admission but has failed to present any evidence of any kind to support his new conclusion which, on its face, is subjective and without support.

In contrast, applicant has submitted herewith a Declaration executed by the applicant as an expert and one skilled in the art to contradict the present conclusion of the Examiner regarding what one skilled in the art could or could not do, based upon the teaching of the specification. Contrary to the presently revised opinion of the Examiner, the applicant has clearly stated that from Example 5, it would be obvious for one skilled in the art to determine without undue experimentation the volume of the reaction buffer. Moreover, from Examples 4, 5 and 14 of the application, it would be obvious to one skilled in the art that a specific composition for the reaction buffer is not essential and that the composition identified on page 48 is exemplary and not critical to enable one to practice the invention. Moreover, applicant has carried out experiments included in Table A in the Declaration under 37 CFR 1.132 to show that a specific composition of a reaction buffer is not required. As explained in the Declaration, in a control assay using a treatment solution without SDS, the measurement value of HCV Panel Serum was as low as or substantially the same as that of normal serum, whereas in the case using a treatment buffer containing SDA in the treatment step wherein any one of three reaction buffers were used in the reaction step, measurement values were substantially the same between the different reaction buffers and were higher than that of the normal serum. From the results shown in Table A, it is clear that the specific composition of the reaction buffer is not essential to satisfy the requirements of enablement under 35 USC 112 to make/use the invention commensurate in scope with the claims.

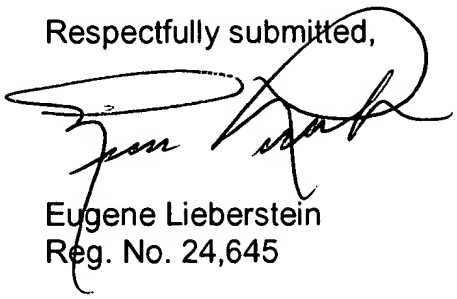
It is also clear from Example 14 in the specification as set forth in the Declaration of applicant under 37 CFR 1.132 that the volume of the reaction buffer is conventional and that a specific volume is not required.

As attested to by applicant in paragraph 7 of the Declaration under 37 CFR 1.132, any person with ordinary skill in the art after reading the subject specification can easily select the volume and a composition for the reaction buffer to be used for the assay of HBV particularly after reading Examples 4, 5 and 14.

The applicant also attempted to explain the concerns of the Examiner regarding whether one skilled in the art would believe that SDS would affect a reaction of the core antigen and the antibody probe.

For all of the above reasons, applicant requests that the rejection of the claims under 35 USC 112, first paragraph, be withdrawn and that the claims be allowed.

Respectfully submitted,



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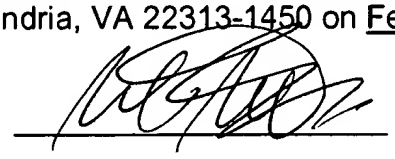
MAILING CERTIFICATE

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 6, 2006.

Signed:  Dated: February 6, 2006